IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
PATENT OPERATION

In re Application of:

Sriwongjanya et al.

Serial No.: **10/617,456** Group Art Unit: --

Filed: **July 11, 2003** Examiner: --

For: **FORMULATION AND PROCESS FOR DRUG LOADED CORES**

New York, NY 10036
September 11, 2003

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

INFORMATION DISCLOSURE STATEMENT

Sir:

The following statement of relevance is submitted with the accompanying Form PTO/SB/08A.

Document Designation	Relevance
AA U.S.P. 4,281,654	Relates to a drug delivery system for controlled ocular therapy.
AB U.S.P. 4,303,637	Relates to medication indicated for ocular hypertension.
AC U.S.P. 4,780,318	Relates to an oral pharmaceutical composition.

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to:
Commissioner for Patents
P.O. Box 1450
Alexamdria, VA 22313-1450
on September 11, 2003

Nicholas P. Chiara, Reg. No. 52,737

Document Designation	Relevance
AD U.S.P. 4,792,452	Relates to a controlled release formulation.
AE U.S.P. 4,874,613	Relates to a taste concealing pharmaceutical dosage unit.
AF U.S.P. 4,892,739	Relates to an osmotic continuous dispensing oral delivery system containing a pharmaceutically acceptable active agent having a improved core membrane adhesion properties.
AG U.S.P. 4,911,707	Relates to a monolithic user-activated transdermal therapeutic system.
AH U.S.P. 4,917,676	Relates to user-activated transdermal therapeutic system.
AI U.S.P. 4,927,640	Relates to controlled release beads having glass or silicon dioxide core.
AJ U.S.P. 4,942,040	Relates to a controlled and extended release pharmaceutical preparation and a process for its preparation.
AK U.S.P. 4,952,402	Relates to a controlled release powder and process for its preparation.
AL U.S.P. 4,957,745	Relates to a controlled release pharmaceutical preparation.
AM U.S.P. 4,996,047	Relates to sustained release drug-resin complexes.
AN U.S.P. 5,001,161	Relates to a pharmaceutical composition comprising metroprolol succinate.
AO U.S.P. 5,019,302	Relates to a method for granulation
AP U.S.P. 5,081,154	Relates to metoprolol succinate and a pharmaceutical preparation containing metoprolol succinate.
AQ U.S.P. 5,169,638	Relates to a buoyant controlled release powder formulation.
AR U.S.P. 5,246,714	Relates to a controlled release drug preparation.

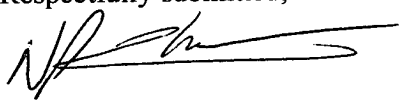
AS U.S.P. 5,288,503	Relates to a cryogel oral pharmaceutical composition containing a therapeutic agent.
AT U.S.P. 5,391,377	Relates to a biphasic release formulations for lipophilic acids.
AU U.S.P. 5,399,358	Relates to a sustained release formulations for 24 hour release of metroprolol.
AV U.S.P. 5,399,362	Relates to once-a-day metoprolol oral dosage form.
AW U.S.P. 5,516,531	Relates to a spherical granules having a core coated with a drug and other excipients.
AX U.S.P. 5,518,730	Relates to a biodegradable controlled release flash flow melt-spun delivery system.
AY U.S.P. 5,681,584	Relates to a controlled release drug delivery device.
AZ U.S.P. 5,700,410	Relates to a method of manufacturing wax matrices.
BA U.S.P. 5,707,656	Relates to pharmaceutical formulations containing a pharmacologically active ionizable substance as well as a process for the preparation thereof.
BB U.S.P. 5,785,976	Relates to solid lipid particles, particles of bioactive agents and methods for the manufacture and use thereof.
BC U.S.P. 6,022,562	Relates to medicinal and/or nutritional microcapsules for oral administration.
BD U.S.P. 6,210,712	Relates to a dosage form having first and second coat.
BE U.S.P. 6,284,271	Relates to a multiple unit effervescent dosage form.
BF U.S.P. 6,287,599	Relates to a sustained release pharmaceutical dosage form with minimized pH dependent dissolution profiles.
BG U.S.P. 6,297,240	Relates to a method for treating ophthalmic disease through fast dispersing dosage forms.
BH U.S.P. 6,365,185	Relates to a self-destructing, controlled release peroral drug delivery system.

BI U.S.P. 6,372,254	Relates to a press coated, pulsatile drug delivery system suitable for oral administration.
BJ U.S.P. 6,383,471	Relates to compositions and methods for improved delivery of ionizable hydrophobic therapeutic agents.
BK U.S.P. 6,491,950	Relates to a controlled release pharmaceutical composition.
CA Physician's Desk Reference 55th Edition (2001), pp. 606-607.	Relates to Toprol XL®.

Full text copies of the prior art are enclosed herewith. It is respectfully requested that this art be considered by the Examiner in the above-entitled application and made of record therein.

Pursuant to 37 C.F.R. §1.97 it is believed that no fee is required for consideration of this Information Disclosure Statement. If a fee is required, the Commissioner is hereby authorized to charge Deposit Account No. 08-1540.

Respectfully submitted,



Nicholas P. Chiara
Reg. No. 52,737

MAILING ADDRESS:
HEDMAN & COSTIGAN, P.C.
1185 Avenue of the Americas
New York, NY 10036
(212) 302-8989

PTO/SB/08A (10-01)
Approved for use through 10/31/2002. OMB 0651-0031
U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

Substitute for form 1449A/PTO

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(use as many sheets as necessary)

Sheet 1 of 3

Compl te if Known	
Application Number	10/617,456
Filing Date	July 11, 2003
First Named Inventor	Mongkol Sriwongjanya
Art Unit	
Examiner Name	
Attorney Docket Number	141-287

U.S. PATENT DOCUMENTS

Examiner Initials*	Cite No.[1]	Document Number: Number - Kind Code[2] (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
	AA	US-4,281,654	08-04-1981	Shell et al.	
	AB	US-4,303,637	12-01-1981	Shell et al.	
	AC	US-4,780,318	10-25-1988	Appelgren et al.	
	AD	US-4,792,452	12-20-1988	Howard et al.	
	AE	US-4,874,613	10-17-1989	Hsiao	
	AF	US- 4,892,739	01-09-1990	Shah et al.	
	AG	US- 4,911,707	03-27-1990	Heiber et al.	
	AH	US- 4,917,676	04-17-1990	Heiber et al.	
	AI	US- 4,927,640	05-22-1990	Dahlinder et al.	
	AJ	US- 4,942,040	07-17-1990	Ragnarsson et al.	
	AK	US- 4,952,402	08-28-1990	Sparks et al.	
	AL	US-4,957,745	09-18-1990	Jonsson et al.	
	AM	US- 4,996,047	02-26-1991	Kelleher et al.	
	AN	US-5,001,161	03-19-1991	Appelgren et al.	
	AO	US-5,019,302	05-28-1991	Sparks et al.	
	AP	US- 5,081,154	01-14-1992	Appelgren et al.	
	AQ	US-5,169,638	12-08-1992	Dennis et al.	
	AR	US- 5,246,714	09-21-1993	Dahlinder et al.	
	AS	US- 5,288,503	02-22-1994	Wood et al.	
	AT	US- 5,391,377	02-21-1995	Barnwell	

FOREIGN PATENT DOCUMENTS

Examiner Initials*	Cite No.[1]	Foreign Patent Document: Country Code[3] -Number[4]- Kind Code[5] (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T[6]

Examiner Signature		Date Considered	

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

[1] Applicant's unique citation designation number (optional). [2] See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. [3] Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). [4] For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [5] Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. [6] Applicant is to place a check mark here if English language Translation is attached.

PTO/SB/08A (10-01)
Approved for use through 10/31/2002. OMB 0651-0031
U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

Substitute for form 1449A/PTO

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(use as many sheets as necessary)

Sheet 2 of 3

Complete if Known	
Application Number	10/617,456
Filing Date	July 11, 2003
First Named Inventor	Mongkol Sriwongjanya
Art Unit	
Examiner Name	
Attorney Docket Number	141-287

U.S. PATENT DOCUMENTS

Examiner Initials*	Cite No.[1]	Document Number: Number - Kind Code[2] (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
	AU	US- 5,399,358	03-21-1995	Baichwal et al.	
	AV	US-5,399,362	03-21-1995	Baichwal et al.	
	AW	US-5,516,531	05-14-1996	Makino et al.	
	AX	US-5,518,730	05-21-1996	Fuisz	
	AY	US-5,681,584	10-28-1997	Savastano et al.	
	AZ	US- 5,700,410	12-23-1997	Nakamichi et al.	
	BA	US- 5,707,656	01-13-1998	Lindstedt et al.	
	BB	US- 5,785,976	07-28-1998	Westesen et al.	
	BC	US- 6,022,562	02-08-2000	Autant et al.	
	BD	US- 6,210,712	04-03-2001	Edgren et al.	
	BE	US- 6,284,271	09-04-2001	Lundberg et al.	
	BF	US-6,287,599	09-11-2001	Burnside et al.	
	BG	US- 6,297,240	10-02-2001	Embleton	
	BH	US-6,365,185	04-02-2002	Ritschel et al.	
	BI	US-6,372,254	04-16-2002	Ting et al.	
	BJ	US- 6,383,471	05-07-2002	Chen et al.	
	BK	US-6,491,950	12-10-2002	Gutierrez-Rocca et al.	
	BL	US-			
	BM	US-			
	BN	US-			

FOREIGN PATENT DOCUMENTS

Examiner Initials*	Cite No.[1]	Foreign Patent Document: Country Code[3] -Number[4]- Kind Code[5] (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T[6]

Examiner Signature		Date Considered	

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

[1] Applicant's unique citation designation number (optional). [2] See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. [3] Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). [4] For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [5] Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. [6] Applicant is to place a check mark here if English language Translation is attached.

PTO/SB/08B (10-01)
Approved for use through 10/31/2002. OMB 0651-0031
U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

Substitute for form 1449B/PTO

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(use as many sheets as necessary)

Sheet 3 of 3

Complet if Known	
Application Number	10/617,456
Filing Date	July 11, 2003
First Named Inventor	Mongkol Sriwongjanya
Group Art Unit	
Examiner Name	
Attorney Docket Number	141-287

OTHER PRIOR ART -- NON PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No.[1]	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T[2]
	CA	Physician's Desk Reference, 55th Edition (2001), pp. 606-607.	

Examiner Signature		Date Considered	

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

[1] Applicant's unique citation designation number (optional). [2] Applicant is to place a check mark here if English language Translation is attached.